

**GOVERNMENT OF INDIA
CHEMICALS AND FERTILIZERS
LOK SABHA**

UNSTARRED QUESTION NO:3648

ANSWERED ON:16.04.2002

EXEMPTION FROM PRICE CONTROL IN THE NEW DRUG POLICY

ANANDRAO ADSUL;GOWDAR MALLIKARJUNAPPA;IQBAL AHMED SARADGI

Will the Minister of CHEMICALS AND FERTILIZERS be pleased to state:

- (a) whether all pharmaceutical formulations having an annual sales turnover upto Rs.10 crore are likely to get a complete exemption from price control in the new drug policy ;
- (b) if so, whether Rs.10 crore exemption limit is irrespective of the market share enjoyed by the drugs formulators in the domestic market ; and
- (c) if so, the time by which the final decision is likely to be taken in this regard ?

Answer

THE MINISTER OF STATE IN THE MINISTRY OF CHEMICALS & FERTILIZERS (SHRI S.B. MOOKHERJEE)

(a) to (c) : Government have recently announced the 'Pharmaceutical Policy-2002', copies of which are available in Parliament library. The Policy provides, inter-alia, as follows :-

(i) The 279 items appearing in the alphabetical list of Essential Drugs in the National Essential Drug List (1996) of the Ministry of Health & Family Welfare and the 173 items, which are considered important by that Ministry from the point of view of their use in various Health Programmes, in emergency care etc., with the exclusion, therefrom of sera & vaccines, blood products, combinations etc., should form the total basket out of which selection of bulk drugs be made for price regulation.

(ii) The ORG-MARG data of March, 2001 would form the basis for determining the span of price control.

(iii) The Moving Annual Total (MAT) value for any formulator in respect of any bulk drug will be arrived at by adding the MAT values of all his single- ingredient formulations of that bulk drug, its salts, esters, stereo-isomers and derivatives, covering all the strengths, dosage forms and pack sizes listed against that formulator in all groups / categories of the ORG-MARG (March, 2001).

(iv) The MAT value for all the formulators, as defined in sub-para

(iii) above, in respect of a particular bulk drug will be added to arrive at the total MAT value in the retail trade.

(v) The MAT value for an individual formulator, in respect of any bulk drug, as arrived at in sub-para

(iii) above, will be the basis for calculating the percentage share of that formulator in the total MAT value arrived at as in sub-para (iv) above, in respect of that bulk drug.

(vi) Bulk Drugs will be kept under price regulation if :-

(a) The total MAT value, arrived at as in sub-para

(iv) above, in respect of any particular bulk drug is more than Rs.2500 lakhs (Rs.25 Crore) and the percentage share, as defined in sub-para

(v) above, of any of the formulators is 50% or more.

(b) The total MAT value, arrived at as in sub-para

(iv) above, in respect of any particular bulk drug is less than Rs.2500 lakhs (Rs.25 Crore) but more than Rs.1000 lakhs (Rs.10 Crore) and the percentage share, as defined in sub-para

(v) above, of any of the formulators is 90% or more.

(vii) All formulations containing a bulk drug as identified above, either individually or in combination with other bulk drugs, including those not identified for price control as bulk drug, will be under price control.'